JAN 2 2 2001

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

## Regulatory Submission Summary
## 510(K) SUMMARY

**SPONSOR:**

Boston Scientific Corporation (BSC)
Microvasive Urology Division
One Boston Scientific Place
Natick, MA 01760

**CONTACT PERSON:**

Lorraine M. Hanley, RAC
Division Manager, Global Regulatory Affairs
or
Linda J. Varroso
Specialist, Global Regulatory Affairs

**DEVICE:** **Contour Polaris™ Ureteral Stents**

Trade Name: Contour Polaris™ Ureteral Stents
Common Name: Ureteral Stent; Splint
Classification Name: Classified Under 21 CFR Part 876, Section 4620. Classified as A Class II Device.

**PREDICATE DEVICE:** **Modified Ureteral Stent (K974541)**

**DEVICE DESCRIPTION:**

The proposed Contour Polaris™ Ureteral Stent is a dual durometer, double pigtail, indwelling ureteral stent.

**INTENDED USE:**

The Contour Polaris™ Ureteral Stent with Hydro-Plus® coating is intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure by a trained physician.

**COMPARISON OF CHARACTERISTICS:**

The proposed device is ***substantially*** to ***equivalent*** currently marketed devices used for facilitating drainage from the kidney to the bladder.

**PERFORMANCE DATA:**

The proposed device is ***substantially equivalent*** to currently marketed ureteral stent devices in terms of performance characteristics tested and biocompatibility.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2001

Linda J. Varroso
Specialist, Global Regulatory Affairs
Boston Scientific Corporation
Microvasive Urology Division
One Boston Scientific Place
NATICK MA 01760

Re: K010002
Contour Polaris™ Ureteral Stents
Dated: December 29, 2000
Received: January 2, 2001
Regulatory Class: II
21 CFR §876.4620/Procode: 78 FAD

Dear Ms. Varroso:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

## Indications for Use Statement



**510(k) Number (if known)**

**Device Name** Contour Polaris™

**Indications for Use** The Contour Polaris™ Ureteral Stent (with or without Hydro-Plus® coating) is intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure by a trained physician.

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

David C. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010002